



949644

SEP 20 2004

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Cellular Wellness Foundation
P.O. Box 1181
Santa Maria, CA 93456-1181

Dear Sir or Madam:

The Food and Drug Administration (FDA) has reviewed your website at www.cancerteate.com. Based on our review, we have determined that your CellularTea™ product violates the Federal Food, Drug, and Cosmetic Act (the Act) because it is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)). You can find the Act and implementing regulations on FDA's web site at www.fda.gov.

Under section 201(g)(1)(B) of the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs. The therapeutic claims on your website establish that CellularTea™ is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The labeling for your product CellularTea™ includes the following disease claims:

- "Burdock was used as an ingredient in alternative cancer treatments. ... [B]urdock also contains polyacetylenes, a chemical that kills disease-causing bacteria and fungi. It will prevent formation of gall stones and kidney stones."
- "[U]se[] Cat's Claw to promote wound healing, and for arthritis, gastric ulcers, inflammation [sic], rheumatism, and tumors. ... Cat's Claw ... has become a popular item for many HIV and cancer patients."
- "Sheep Sorrel ... was used as a remedy for cancer. The herb relieves internal ulcers and, when used externally, helps clear skin problems such as herpes, eczema, and ringworm."
- "Watercress has been used for gout, scurvy, anemia, and tuberculosis."
- "[U]se of red clover extract by men with prostate cancer, led to noticeable anti-cancer results in their prostate. The isoflavones in red clover may assist in preventing certain forms of cancer such as breast and prostate."

- “[T]he CellularTea™ formula may be so effective not only against cancer but against a number of other diseases which include: Arthritis, Asthma, Allergies, Alzheimer’s, ... Chronic Fatigue Syndrome, Diabetes, ... Hypoglycemia, Impotence, Malignancies, Multiple Sclerosis, Parkinson’s”
- “Listed below are some conditions which people have attributed to the effects of the CellularTea™
 - Stops hemorrhages, and builds up the blood
 - Boosts immune system (**while undergoing cancer therapy**)
 - Helps intestinal burns from radiation therapy
- “Answer to Cancer”

In addition, because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act (21 U.S.C. § 321(p)). Under section 505(a) of the Act (21 U.S.C. 355(a)), a new drug may not be legally marketed in the United States without an approved New Drug Application.

In addition, your website states that the “herbs in CellularTea™ are formulated in an FDA approved laboratory under FDA guidelines to ensure a high standard of quality.” The promotion of your product in this manner implies FDA approval or sanction of your product and its purported uses. Because FDA does not approve laboratories, this part of the statement causes your product to be misbranded under section 502(a) of the Act (21 U.S.C. § 352(a)) because these statements are false and misleading. In addition, FDA’s current good manufacturing practice regulations for drugs establish minimum requirements to ensure that a drug meets the requirements of the Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. If your manufacturing practices for your “CellularTea™” product do not meet the requirements of 21 CFR Parts 210 and 211, then your statement that this product is formulated under FDA guidelines also misbrands your product under section 502(a) because it is false and misleading.

Finally, in July 2004, FDA obtained a product called “CancerTea” from your website. The label for this product includes disease claims such as “Answer to Cancer.” Further, the name of this product is a disease claim because it implies that it is for use in the cure, mitigation, treatment, or prevention of cancer. Although this product does not appear to be currently marketed on your website, we note that a picture of the “CancerTea” product appears on your website’s order page for CellularTea™ at <http://www.cancertea.com/order/sales.shtml> and <http://www.cancertea.com/order/retail.shtml>. Be advised that the marketing of the “CancerTea” product with this product name and labeling claims would violate the Act because it would be promoted for conditions that cause the product to be an unapproved new drug under sections 201(p) and 505(a) of the Act.

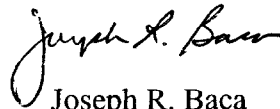
The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm and all labeling for such products comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to Jennifer Thomas, Compliance Officer, U.S. Food and Drug Administration, 5100 Paint Branch Parkway (HFS-607), College Park, MD 20740.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph R. Baca". The signature is fluid and cursive, with the first name "Joseph" being more prominent.

Joseph R. Baca
Director, Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: CancerTea Foundation
Box 6
Arroyo Grande, CA 93421